

**REMARKS**

Claims 73 and 74 are pending in the present application. No claims have been amended, cancelled, or added by virtue of this response. Accordingly, claims 73-74 are currently under consideration.

***Interview Summary***

An interview summary was filed on August 18, 2008 and reproduced herein for the Examiner's convenience.

Applicants express their gratitude for the in-person interview between Examiner Vu and Applicants' representative Catherine Polizzi, on July 16, 2008. The time and consideration of the Examiner is greatly appreciated.

During the interview, Examiner Vu and Applicants' representative discussed the pending claims and the art of record, including differences in the process of making the compositions.

***Withdrawn Rejection***

Applicants acknowledge with appreciation that the rejection of claim 73 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement is withdrawn.

***Double Patenting***

Claims 73 and 74 stand rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over U.S. Patent Nos.: 6,537,579; 5,362,478; 5,498,421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686.

As noted by the Examiner, Applicants will address these rejections, if maintained, when the pending claims are otherwise found allowable.

***Claim Rejections – 35 USC § 102(b)***

Claims 73 and 74 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Liversidge et al. (US 5,399,36, “Liversidge”) in light of Markus et al., J. Am. Chem. Soc., 1957, 79(1):134-139. Applicants respectfully traverse this rejection.

Applicants respectfully submit that Liversidge does not disclose albumin that is crosslinked by intermolecular disulfide bonds. On the contrary, Liversidge states that “[t]he surface modifier does not chemically react with the anticancer agent *or itself*.” See column 4, lines 56-57 of Liversidge (emphasis added). The reference further states that the “individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages.” See column 4, lines 57-59 of Liversidge.

The Examiner found Applicants’ arguments non-persuasive, reasoning that “LIVERSIDGE’s ‘essentially free of intermolecular crosslinkages’ refers to the non-intermolecular crosslinkages prior to the high shear milling and ultrasonication similar to Applicant’s albumin prior to high shear milling.” Page 3 of the Office Action. Applicants respectfully disagree.

Liversidge states that “[t]he particles of this invention contain an anticancer agent as described above having a surface modifier adsorbed on the surface thereof.” Column 3, lines 55-58. It further states,

The surface modifier is adsorbed on the surface of the anticancer agent in an amount sufficient to maintain an effective average particle size of less than about 1000 nm. The surface modifier does not chemically react with the anticancer agent or itself. Furthermore, the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages.

Column 4, lines 53-59.

A person of ordinary skill in the art reading the reference would understand that Liversidge refers to the crosslinking characteristics of the surface modifiers adsorbed to the surface of the formed particles, not those prior to the high shear milling or ultrasonication.

The Examiner points to column 6, lines 58-60 of Liversidge, which discloses use of ultrasonic energy having a frequency of 20-80 kHz for a time of about 1 to 120 seconds. The Examiner further points to column 6, lines 34-39 of Liversidge, which discloses that high shear milling can decrease the milling time from five days or longer to times of one minute. The Examiner states that an increase in shear force would inherently result in the intermolecular crosslinking of albumin. Applicants respectfully disagree.

Applicants respectfully submit that the disclosures relied upon by the Examiner do not disclose applying ultrasonic energy or high shear milling to albumin. In fact, in light of the express statement in Liversidge that the surface modifiers adsorbed on the surface of the particles do not chemically react with themselves and further are essentially free of intermolecular crosslinkages, one of the ordinary skill in the art would understand that Liversidge's discussion about ultrasonic energy and high shear milling would be inapplicable to molecules that form intermolecular crosslinkages under those conditions, such as albumin.

Applicants respectfully submit that inherent anticipation requires that the inherent characteristics in question must necessarily be present in the disclosure of the prior art. *See* MPEP § 2112(IV). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flow from the teaching of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); *See also* MPEP § 2112(IV). As discussed above, Liversidge does not disclose applying ultrasonic energy or high shear milling to albumin. Specifically, Liversidge discloses that the surface modifiers do not chemically react with themselves. Liversidge further discloses that the surface modifiers adsorbed on the particles are essentially free of intermolecular crosslinkages. One of ordinary skill in the art reading the reference would understand that the general language in Liversidge about ultrasonic energy and high shear milling would not be applicable to albumin. As such, it is not reasonable to conclude

that Applicant's claimed invention would necessarily flow from the disclosure of Liversidge about ultrasonic energy and high shear milling.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).


**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 638772000126. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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